UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MICHELE ERKAN, on behalf of herself and her minor child, Plaintiff, v. NEW ENGLAND COMPOUNDING PHARMACY, INC d/b/a NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., BARRY CADDEN, LISA CONIGLIARO CADDEN, GREGORY CONIGLIARO, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, and GLENN A. CHIN, Defendants.	Civil Action No.:

COMPLAINT AND JURY DEMAND

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I. INTRODUCTION

1. On September 26, in the wake of dozens of cases of fungal meningitis associated with New England Compounding Company's injectable steroid methylprednisolone acetate, state agents raided the New England Compounding Center's lab in a strip mall on Waverly Street in Framingham, Massachusetts. What they observed shocked the FDA, the Massachusetts Department of Public Health, Congress, and the public.

2. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last ditch effort to wash away NECC's sins, the clean rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the clean rooms were covered with dirt and white fuzz. And the metal shelf in the very clean room used to prepare methylprednisolone was covered in a reddish-brown cloudy substance.

3. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even tried to get rid of these microbial contaminants.

4. Eighty-three out of 321 observed vials from one of three recalled lots contained a greenish-black substance visible to the human eye. 17 other vials contained a white filamentous material. 50 of 50 tested vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least 40 fungal meningitis cases.

5. On or about November 10, 2011, Michele Erkan received a steroid injection from the Wellspan Interventional Pain Management facility, an FDA confirmed recipient of New England Compounding Center's contaminated steroid product. Several days after her injection, Ms. Erkan developed high fever, severe headache, neck stiffness, nausea, vomiting, and sensitivity to light and subsequently received a lumbar puncture (spinal tap). Ms. Erkan was diagnosed with fungal meningitis. She was bed-ridden for over a month. Ms. Erkan has suffered, and continues to suffer, direct injury as a result of the defendants' negligent misconduct.

II. PARTIES

6. Plaintiff Michele Erkan is an adult resident of Red Lion, Pennsylvania, and, at all relevant times, was a resident and citizen of Pennsylvania. On or about November 10, 2011, and on two prior occasions, Ms. Erkan received a caudal epidural steroid injection from the Wellspan Interventional Pain Management facility in York, Pennsylvania. The FDA has confirmed that Wellspan purchased products from New England Compounding Center. In the immediate days following the November 10, 2011 injection, Ms. Erkan developed high fever, severe headache, neck stiffness, nausea, vomiting, and sensitivity to light and subsequently received a lumbar puncture (spinal tap) confirming a diagnosis of fungal meningitis. She was bed-ridden for over a month suffering from nausea, continued vomiting, severe, headaches, and hypersensitivity to light. She continues to suffer from severe headaches, hearing loss, short-term memory loss, and remains on a variety of medications. Since her bout with fungal meningitis, Ms. Erkan has been unable to work, forced to rely on social security disability checks, and suffers from severe depression. Ms. Erkan was and continues to be directly injured as a result of the defendants' misconduct. Plaintiff Michele Erkan brings this action on her own behalf and on behalf of her minor son, Gerrit Erkan.

7. Ms. Erkan has four children, the youngest of which, Gerrit Erkan, is twelve years of age and lives with his mother. Gerrit Erkan is dependent upon Ms. Erkan for the management of his day-to-day needs as well as for emotional guidance and support. Ms. Erkan was hospitalized as a result of her meningitis putting Gerrit Erkan in fear of losing the companionship of his mother. Upon release from the hospital, Ms. Erkan remained bedridden and unable to fully care for her son's daily physical and emotional needs.

8. Defendant New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), is a Massachusetts corporation located at 697 Waverly Street, Framingham, MA, formerly of 701 Waverly Street, Framingham, MA. NECC is engaged in the manufacturing, marketing, and selling of various drugs, including the injectable steroid methylprednisolone acetate. New England Compounding Pharmacy, Inc.'s registered agent is Gregory Conigliaro, 697 Waverly Street, Framingham, MA.

9. Defendant Ameridose, LLC ("Ameridose"), is a Massachusetts limited liability company with its principal offices located at 201-205 Flanders Road, Westborough, MA, formerly of 701 Waverly Street, Framingham, MA. Ameridose is a sister company to NECC, manufactures and sells drug products, and is owned by the same individuals as NECC. Ameridose has been closed since October 10, 2012. Authorities are conducting an ongoing investigation of its facilities. Ameridose, LLC's registered agent is Gregory Conigliaro, 205 Flanders Road, Westborough, MA.

10. Defendant Medical Sales Management, Inc. ("MSM"), is a Massachusetts corporation with its principal offices located at 701 Waverly Street, Framingham, MA. Medical Sales Management, Inc.'s registered agent is Gregory Conigliaro, 697 Waverly Street, Framingham, MA.

11. Defendants NECC, Ameridose, and MSM have common ownership and currently, or have previously, utilized the same facilities and resources for their businesses.

12. Defendant Barry J. Cadden resides at 13 Manchester Drive, Wrentham, MA. Until recently, he was an owner, President, Head Pharmacist, and Director of Pharmacy at NECC. He oversaw the day to day operations of NECC and, upon information and belief, compounded medications himself. Barry Cadden was a founder and Manager of Ameridose, and was involved in Ameridose's day to day operations as well. Mr. Cadden was the Treasurer and Director of MSM.

13. Defendant Gregory Conigliaro resides at 1 Mountain View Drive, Framingham, MA, and is a principal owner, Treasurer, Secretary, Vice President, and Directror of NECC. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. He is founder and Manager of Ameridose and involved in Ameridose's day to day operations. Mr. Conigliaro is Secretary and Director of MSM.

14. Defendant Lisa Conigliaro Cadden (sometimes referred to as Lisa Cadden, Lisa Conigliaro, or Lisa Cadden Conigliaro) resides at 13 Manchester Drive, Wrentham, MA, and is a board member, Director, and pharmacist at NECC. Lisa, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

15. Defendant Douglas Conigliaro resides at 15 Hale Drive, Dedham, MA, and is the President and Director of MSM. Douglas, upon information and belief, is involved in the day to day operations of NECC, Ameridose, and MSM.

16. Defendant Carla Conigliaro resides at 2110 Fawsett Road, Winter Park, FL, and is a Director at NECC.

17. Defendant Glenn A. Chin resides at 173 Mechanic Street, Canton, MA, and is an employee and leader at NECC. Chin was present during the state and federal investigations of NECC's premises.

III. JURISDICTION

18. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c).

IV. STATEMENT OF FACTS

A. The Conigliaro family businesses.

1. Conigliaro Industries's recycling plant

20. In 1990, Gregory Conigliaro opened Conigliaro Engineering in an old industrial building on Waverly Street in Framingham, Massachusetts. In 1991, the company incorporated under the new name Conigliaro Industries, Inc. and began recycling plastic, metal, glass, paper. It made money by converted detergent bottles into recycling bins, molded Styrofoam lunch trays into flower pots, and turned plastic computer casings into pothole filler.

21. Early on, Gregory Conigliaro branched out into real estate, starting GDC Holdings Inc. and GDC Properties Management LLC.

22. In April 2003, Conigliaro Industries opened the first U.S. commercial plant that shreds and recycles mattresses, including polyurethane foam parts. The mattress recycling operation was planned and developed by Tony Conigliaro, the Vice President of Engineering and Gregory's father. The company built a 2,500 square foot mattress shredding facility located next to its 90,000 square foot plant on a seven acre parcel in Framingham. The

company also earmarked another 5,000 square feet of its main factory space for the venture and utilizes its 30 docks for the operation.

23. Mattresses from schools, prisons, and hospitals are put through a giant shredder that separates the polyurethane foam from the springs and wood frame and bales the foam. Gregory Conigliaro claimed that the company could recycle mattresses at the rate of one each minute.

24. Today, Conigliaro Industries touts itself as a pioneer in the field of "Total Recycling" and recycles over 150 different materials, including rubber, plastics, and metal. The business operates out of an 88,000 square foot facility located at 701 Waverly Street, in the large Framingham complex owned by Gregory Conigilaro's real estate companies, GDC Holdings Inc. and/or GDC Properties Management LLC.

2. Gregory Conigliaro, Barry Cadden, and Douglas Conigliaro found NECC.

25. In 1998, well after the Conigliaro recycling facility and real estate companies were up and running, the Conigliaro family decided to branch out into pharmaceutical compounding. Gregory Conigliaro's sister, Lisa Conigliaro Cadden, and her husband, Barry Cadden, were both pharmacists. Gregory Conigliaro and Barry Cadden co-founded New England Compounding Pharmacy, Inc., known as New England Compounding Center (NECC). NECC opened in the same Waverly Street building that housed the recycling plant and real estate businesses.

26. Another Conigliaro brother, Dr. Douglas Conigliaro, was a disgraced anesthesiologist. He allegedly punctured a 64-year-old woman's spine during a 1995 operation to insert a pump to deliver painkillers. The woman became paralyzed and died a couple years later. The suit ultimately settled for $1 million and Douglas Conigliaro was fined $10,000 by the Florida state medical board. Sixty-five percent (65%) ownership of NECC was originally

put in the name of Douglas Conigliaro's wife, Carla Conigliaro, a nurse. Carla Conigliaro was originally listed as the company's president. Douglas Conigliaro was personally involved with NECC from the beginning.

27. Barry Cadden ran NECC, typically wearing scrubs to work. Cadden held positions as the President, Chief Pharmacist, and Director of NECC. Gregory Conigliaro provided financial advice and usually wore a shirt and tie. Lisa Conigliaro Cadden, was a board member and worked as a pharmacist at NECC. According to former employees, Douglas Conigliaro was heavily involved in the day-to-day operations of NECC, though employees were told not to mention his involvement to potential clients or customers.

3. Medical Sales Management

28. In or around 2002, the Conigliaros opened another company in the same Framingham building, now called Medical Sales Management Inc. (MSM). MSM, led by Douglas Conigliaro, provided advertising and marketing services for NECC. As the sales arm for New England Compounding, Medical Sales Management promoted the compounding business at trade shows across the country, and its sales force aggressively worked the phones, cold-calling new customers and reaching out to existing ones. It also helped manage the company's computer operations.

29. Later, Medical Sales Management provided the same services to Ameridose.

4. Ameridose

30. In 2006, Gregory Conigliaro and Barry Cadden launched Ameridose, originally located in the same Framingham building. Former employees say the Conigliaro family found a new opportunity, selling a much-needed service to hospitals: prefilling syringes and breaking down vats of liquid medications into smaller intra-venous bags for individual treatments. Historically hospitals did much of that work themselves. But new federal regulations required

hospitals to go through more elaborate steps to handle sterile preparations, making it more costly and complicated.

31. Unlike New England Compounding, Ameridose has a manufacturing license from the US Food and Drug Administration, allowing it to ship medications in bulk without obtaining individual prescriptions.

32. A few years in, Ameridose leased additional office space in Westborough, Massachusetts. This additional space was, in part, to accommodate the growing Medical Sales Management sales force. Ameridose officially changed its address to the Westborough facility last year.

33. In 2008, Ameridose had 50 employees. As of this year, that number had skyrocketed to 400.

34. Ameridose is currently under investigation for similarly deficient manufacturing and sterilization practices as NECC.

5. Alaunus Pharmaceutical

35. In 2009, Gregory Conigliaro and Barry Cadden founded yet another company, Alaunus Pharmaceutical LLC. Alaunus identifies, develops, and markets generic pharmaceutical products to physicians and pharmacies throughout the United States. It has several Abbreviated New Drug Applications on file with the FDA though apparently no approved products. Alaunus is located at 687 Waverly Street, in the same office park as NECC and the recycling facility.

B. Background on compounding pharmacies.

36. According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient.

Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.

37. NECC's webpage claimed compounding allows doctors to prescribe prescription drugs that are "no longer manufactured, persistently backordered because of production shortages, not commercially available in the dosage form the patient needs (e.g., preservative free)."

38. In Massachusetts, compounding pharmacies must have a prescription from an individual patient in order to create a drug.

39. Compounding pharmacies generally following testing guidelines established by the U.S. Pharmacopeia (USP), a nonprofit private group that develops standards of drug quality. According to an industry group, the International Academy of Compounding Pharmacists, adherence to the USP standards is expected. Some Massachusetts compounding pharmacies, including Microtest Laboratories, typically test more than the number of samples required by the USP standards to confirm sterility.

40. Compounding industry standards were created for pharmacists making small batches of medicines for individuals, not for the commercial production of large batches.

C. History of the regulation of compounding.

41. Though FDA has consistently maintained it has authority over compounding, it has traditionally elected not to exercise its enforcement discretion.

42. In 1996, the commissioner of the Food and Drug Administration, warned Congress that drug-compounding pharmacies would create a "shadow industry" of unapproved drugs that "could result in serious adverse effects, including death." In the wake of the NECC disaster, the former Commissioner's words have been described as "eerily prophetic."

1. Congress gave the FDA the authority to regulate compounding.

43. In 1997, Congress amended the Food Drug and Cosmetic Act to address compounded drugs. Under section 503A, drug products that were compounded by a pharmacist or physician on a customized basis for an individual patient were entitled to exemptions from three key provisions of the Act: (1) the adulteration provision of section 501(a)(2)(B) (concerning the good manufacturing practice requirements); (2) the misbranding provision of section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) the new drug provision of section 505 (concerning the approval of drugs under new drug or abbreviated new drug applications). But to qualify for these exemptions, the product must be made for an individual patient with a valid prescription noting the compound is necessary:

> the drug product is compounded for an *identified individual patient* based on the unsolicited receipt of a *valid prescription* order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is *necessary* for the identified patient, [and] if the drug product meets the requirements of this section.

44. 503A required that compounding must be done by a licensed pharmacist or licensed physician. The pharmacist or physician must use bulk drug substances that (1) comply with United States Pharmacopeia or National Formulary monographs and the United States Pharmacopoeia chapter on pharmacy compounding, (2) are manufactured by an establishment registered under section 360, and (3) are accompanied by valid certificates of analysis for each bulk drug substance. If the compounder uses ingredients other than bulk drug substances, those ingredients must also comply with the USP and NF monographs and the US Pharmacopoeia chapter on pharmacy compounding.

45. 503A also provided that compounders may not compound drug products that have been withdrawn or removed from the market because they are unsafe or not effective.

Nor many compounders regularly compound or compound in inordinate amounts, drug products that are essentially copies of a commercially available drug product.

46. 503A also stated that a pharmacy, pharmacist, or physician may only compound a drug if it does *not* advertise or promote the compounding of any particular drug, class of drug, or type of drug. Compounders may only advertise or promote the compounding service provided by the license pharmacist or physician.

47. Section 503A of the Act took effect on November 21, 1998.

2. The Supreme Court found the advertising restrictions in 503A invalid.

48. In November 1998, seven compounding pharmacies challenged the solicitation and advertising prohibitions of section 503A as an impermissible regulation of commercial speech. The U.S. District Court for the District of Nevada ruled in the plaintiffs' favor. FDA appealed to the U.S. Court of Appeals for the Ninth Circuit. On February 6, 2001, the Court of Appeals declared section 503A invalid in its entirety (Western States Medical Center v. Shalala, 238 F.3rd 1090 (9th Cir. 2001)). The government petitioned for a writ of certiorari to the U.S. Supreme Court for review of the circuit court opinion. The Supreme Court granted the writ and issued its decision in the case on April 29, 2002.

49. The Supreme Court affirmed the 9th Circuit Court of Appeals decision that found section 503A of the Act invalid in its entirety because it contained unconstitutional restrictions on commercial speech (*i.e.*, prohibitions on soliciting prescriptions for and advertising specific compounded drugs). The Court did not rule on, and therefore left in place, the 9th Circuit's holding that the unconstitutional restrictions on commercial speech could not be severed from the rest of section 503A. Accordingly, all of section 503A is now invalid.

3. FDA's guidance on compounding.

50. In May 2002, shortly after the Supreme Court's decision, the FDA issued guidance to FDA staff and the compounding industry on the factors the Agency would consider in exercising its enforcement discretion regarding pharmacy compounding.

51. The FDA noted that pharmacists have traditionally compounded reasonable quantities of human drugs in response to a valid prescription for an individual patient. However, the Agency noted that "an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and violates the [Food, Drug, and Cosmetic] Act."

52. The FDA specifically noted that "some firms receive and use large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription" and that "[p]harmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Act as manufacturers."

53. The FDA concluded that it would continue to defer to state authorities regarding "less significant violations" but would "seriously consider enforcement action" when "the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act." The guidance listed factors the FDA would consider in deciding whether to take action, including:

- Anticipatory compounding,
- Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs,

- Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility,
- Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements,
- Using commercial scale manufacturing or testing equipment for compounding drug products, and
- Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

D. NECC touted its products as high quality and sterile.

54. New England Compounding Center is a compounding-only pharmacy that claimed to be "dedicated to providing the highest quality compounded medications and services to patients and prescribers."

55. NECC compounded a number of injectable drugs, including drugs intended to be injected into the spine (epidural injections).

56. NECC's website claimed that its pharmacy facility "was designed and constructed as a 'compounding-only" lab to provide an ideal environment for our staff to produce only the highest quality compounded medications."

57. NECC claimed it was "USP Chapter 797 compliant" and that its pharmacists "formulate all medications with only the highest grade chemicals in the state-of-the-art compounding facility." NECC also claimed that "chemicals are obtained only from FDA registered chemical distributors."

58. An internal NECC review of the first quarter of 2012 stated that its testing of product "exceeds basic USP <797> compliance and ensures product quality." Meaning, the pharmacy contended that it was following industry USP guidelines intended to reduce the risk of contamination.

59. NECC claimed that samples from final batch lots were sent to an independent FDA registered analytical lab for sterility and stability testing. NECC claimed that "[t]ested medications are quarantined and dispensed only after the sample has tested negative for endotoxin and microbial contamination."

60. NECC claimed that its pharmacists "[f]ollow national standards of practice for sterile product preparation as set forth by professional associations such as the American Society of Health-System Pharmacists (ASHP) and the United States Pharmacopeia (USP)."

E. FDA's September 2004 warning letter.

61. On September 23, 2004, FDA investigators and the Massachusetts Board of Pharmacy began inspecting New England Compounding's facilities at 697 Waverly Street in Framingham, MA. They completed the inspection on January 19, 2005.

62. On October 1, 2004, Barry Cadden and/or New England Compounding sent a letter to FDA's New England District Office concerning questions presented during the referenced inspection.

63. On December 4, 2006, the FDA sent a warning letter to Barry Cadden, "Director of Pharmacy and Owner, New England Compounding Center." The FDA noted that it considered compounded drugs to be new drugs within the meaning of the Food Drug and Cosmetic Act. And, as new drugs, "compounded drugs may not be introduced into interstate commerce without FDA approval."

F. Meningitis

64. Meningitis is an infection of the membranes covering the brain and spinal cord (meninges). Primary symptoms include: fever, chills, altered mental status, nausea, vomiting, sensitivity to light (photophobia), severe headache, and neck stiffness. Meningitis is typically diagnosed by lumbar puncture (spinal tap) that collects spinal fluid (cerebrospinal fluid). The

fluid is then tested to determine the infection's exact cause for an appropriate course of treatment. When a lumbar puncture is not possible, a diagnosis may be presumed based on the constellation of symptoms. Complications and risks from meningitis include: brain damage, buildup of fluid between the skull and brain (subdural effusion), hearing loss, hydrocephalus, and seizures.

65. Meningitis can be caused by several factors including bacteria, viruses, and fungus. Fungal meningitis is rare and people with weak immune systems are at a higher risk of contraction.

66. Meningitis is an infection that usually spreads through the blood to the spinal cord. It is caused by the introduction of a bacteria, virus, or fungus into the central nervous system or from an infected body site infection next to the central nervous system. Primary symptoms include: fever, altered mental status, nausea, vomiting, sensitivity to light (photophobia), headache, and stiff neck.

67. The typical incubation period for contracting fungal meningitis from the tainted steroid is one to four weeks after injection, though can be far longer and symptoms can be mild in nature. As with any variety of meningitis, it is important to perform a lumbar puncture (spinal tap) to collect and test spinal fluid (cerebrospinal fluid) and determine the exact type of fungus for an appropriate course of treatment. Appropriate laboratory tests may vary depending on the type of fungus suspected. Treatment of fungal meningitis typically requires long courses of high dose antifungal medications but treatment length can vary depending on the state of the immune system and type of fungus.

G. The fungal meningitis outbreak.

1. Meningitis cases are linked to NECC's epidural steroid injections

68. *September 21, 2012* **–** The Centers for Disease Control was notified by the Tennessee Department of Health of a patient with the onset of meningitis approximately nineteen days following an epidural steroid injection at a Tennessee ambulatory surgical center. All initial cultures of cerebrospinal fluid (CSF) and blood were negative for any potential infection; subsequently the patient had a fungus isolated from CSF by fungal culture.

69. *September 24, 2012* – In the late evening hours, the Tennessee Department of Health notified the Massachusetts Department of Public Health (DPH) about a cluster of six fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. The Tennesee Department of Health noticed this cluster of cases because of the rarity of fungal meningitis. These patients all received injections of methylprednisolone acetate 80 mg/ml preservative free compounded by NECC.

2. The FDA and DPH begin investigating NECC.

70. *September 25, 2012* – The Massachusetts DPH, Board of Registration in Pharmacy, and Bureau of Infectious Diseases convened a multi-agency meeting with the Tennessee Department of Health, the U.S. Centers for Disease Control and Prevention (CDC), the FDA, and NECC. At the demand of DPH staff, Barry Cadden and Gregory Conigliaro provided documentation of facilities that received medications from three lots of methylprednisolone acetate suspected as linked to the fungal infections. According to those lists, the suspected lots contained 17,676 doses and were distributed to more than 14,000 patients in 23 states.

71. *September 26, 2012* – NECC recalled three lots of preservative-free methylprednisolone acetate: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26,

BUD 12/26/2012; Lot #08102012@51, BUD 2/6/2013. Approximately 3,000 doses were quarantined or returned through recall. This meant that around 14,000 people received contaminated injections.

72. Also on September 26, 2012, DPH began its investigation of NECC's facility. When DPH arrived at NECC, investigators found NECC employees cleaning compounding areas and conducting environmental testing. The investigators also detected signs of black decontamination in the compounding areas.

73. Also on or before September 26, 2012, NECC terminated many of their staff. After September 26, 2012, the majority of NECC employees were no longer on site.

74. *September 27, 2012* – From September 27, 2012 through September 30, 2012, DPH and FDA coordinated to plan a collaborative investigation of NECC.

75. *September 28, 2012* – Investigators identified a case of presumed fungal meningitis outside of Tennessee, indicating possible contamination of a widely-distributed medication.

76. *October 1, 2012* – DPH and FDA began a joint investigation of NECC. Investigators were shown examples of methylprednisolone products that were labeled as patient-specific. But NECC did not have individual prescriptions. Instead, it had lists of patients generated by a clinical facility and provided to NECC to obtain the product. NECC stated the list of names was considered to be an authorized prescription by the physician. This practice is not in accordance with Massachusetts regulations.

77. DPH issued a formal Quarantine Notice pursuant to M.G.L. c. 94C sections 13 and 189A, and M.G.L. c. 112 sections 30 and 42A, in accordance with the CDC's epidemiological work. The Notice directs that all raw materials, all non-sterile and sterile

products located at NECC used in the compounding of methylprednisolone acetate and all inventory on the premises prepared for dispensing and stored at the pharmacy should be quarantined and not disposed of without DPH's approval.

78. *October 2, 2012* – DPH and FDA observed visible black particulate matter in sealed vials of purportedly sterile methylprednisolone acetate returned to NECC. Inconsistencies in sterilization of processed materials were identified through review of NECC's records. The board voted to obtain a Voluntary Surrender of NECC's license or to initiate action to issue a Temporary Order of Summary Suspension.

3. NECC surrenders its pharmacy license and recalls all of its products.

79. *October 3, 2012* – NECC surrendered its pharmacy license. It ceased all production and initiated recall of all methylprednisolone acetate and other drug products prepared for injections in and around the spinal cord (known as intrathecal administration). DPH also notified Massachusetts providers to cease use of all NECC products.

80. *October 4, 2012* – a total of 35 cases in six states had been identified with a "clinical picture" consistent with fungal infection, five deaths had been reported, and fungus had been identified in specimens obtained from five patients. The CDC announced that all infected patients received preservative-free methylprednisolone acetate from among the three lots voluntarily recalled by the New England Compounding Center.

81. *October 5, 2012* – DPH and FDA investigators noted visible contaminants in additional sealed recalled vials of methylprednisolone acetate. The particulate matter was noted in both vials labeled with patient-specific information and vials labeled without patient-specific information (in violation of Massachusetts regulations). DPH and FDA issued a nationwide alert to providers and facilities across the country, informing them about the particulate matter.

82. *October 6* – NECC, in conjunction with the FDA, CDC, and Massachusetts Board of Registration in Pharmacy's investigation, recalled all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts "due to the potential risk of contamination."

H. The FDA and Massachusetts Board of Pharmacy's findings.

83. Beginning September 26, 2012, the Massachusetts Department of Public Health (DPH) and the FDA began an investigation of NECC's facility to identify the root causes of the fungal meningitis epidemic.

84. DPH obtained documentary evidence (including photographs), reviewing and obtaining copies of Standard Operating Procedures, observational findings, reviewing and obtaining copies of all policies and procedures, reviewing batch records and interviewing NECC staff. The FDA conducted product testing and took environmental samples of various areas of the facility to test for contaminants.

85. From the beginning of their investigation, the DPH and FDA identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk." The FDA reported that it had detected fungal contamination by microscopic examination of particulate matter taken from a sealed vial of methylprednisolone acetate collected from NECC. The FDA also noted that "foreign material" had also been observed in other vials produced by NECC that were collected by FDA during an inspection. FDA further stated that it was in the process of further identifying the fungal contaminant and conducting microbial testing.

1. DPH's Preliminary Findings

86. On October 23, 2012, the DPH released its preliminary investigation findings.

87. NECC distributed two of the recalled lots of methylprednisolone acetate (preservative free) 80 MG/ML *before* receiving results of sterility testing. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were sent out before the final sterility tests results were received. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. At least eleven shipments of product were sent out before the final sterility test results were received. NECC's records claim that these sterility tests found no contamination, but the DPH questioned whether NECC's sterility testing methods were adequate.

88. The DPH observed visible black particulate matter in several recalled sealed vials of methylprednisolone acetate from Lot 08102012@51.

89. NECC did not follow either the proper USP 797 autoclaving sterilization procedure or its own standards operating procedures. The DPH noted NECC's systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

90. DPH found that NECC distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license. If NECC had been licensed as a manufacturer with the FDA, it would have been subject to additional levels of scrutiny.

91. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

92. NECC did not conduct patient-specific medication history and drug utilization reviews, as required by regulations.

93. Powder hoods, in tended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 797. Residual powder was visually observed, which could lead to contamination of compounded medications.

94. "Tacky mats" used to trap dirt, dust, and other potential contaminants from shows prior to clean room entry were visibly soiled with debris, in violation of USP 797.

95. A leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water.

2. FDA's initial findings and Form 483 report

96. On October 18, 2012, the FDA released definitive laboratory confirmation of the presences of fungal contaminants in sealed vials of methylprednisolone acetate in a suspect lot prepared by NECC.

97. On October 26, 2012, the FDA released a copy of the FDA form 483 issued to New England Compounding Center. The FDA issues a 483 at the end of an inspection when the investigators believe that they observed conditions or practices that indicate violations of the Food, Drug, and Cosmetic Act or attendant regulations.

98. The FDA observed and has since confirmed contaminated products and listed a number of observations regarding conditions in the Clean Room 2 at NECC's Framingham facility.

99. During an October 2, 2012 inspection, the FDA observed that approximately 83 vials of a bin of 321 vials of methylprednisolone acetate from Lot #08102012@51 (shipped between August 17, 2012 and September 25, 2012) to contain a greenish black foreign matter. Seventeen vials from the same bin contained white filamentous material.

100. The FDA's sterility analysis of a sample confirmed the presence of "viable microbial growth" in all of the 50 vials tested. One vial showed fungal morphological features. Yet NEC's own sterility sample from the same lot reported the batch was sterile.

101. The FDA reported that NECC's formula worksheets state that the raw materials used to create their drug products are sterile, but the Pharmacy Director told the FDA that NECC uses non-sterile active pharmaceutical ingredients (API) and non-sterile raw materials to formulate preservative free methylprednisolone acetate, triamcinolone, and other injectable suspensions. The inspection confirmed that the labeling for the methylprednisolone acetate API and other raw materials did not indicate that they were sterile.

102. NECC claimed that its "steam autoclave cycle" "sterilized" suspensions formulated with non-sterile materials. The FDA noted that NECC provided no documentation or evidence that this autoclave procedure worked. In fact, the FDA reported tarnish, condensation, and discoloration in the autoclaves. The FDA also observed puddles of water in the base of the autoclave chamber.

103. The FDA also reported that on at least 26 occasions between January 2012 and September 2012, NECC's internal environmental monitoring program recorded bacteria and mold in the clean rooms used to produce "sterile" drug products. This included at least 38 instances where the level of bacteria recorded was above the level where NECC was supposed to take action ("action level" or "action limit") and 18 instances where the level of mold reported was above NECC's action level. According to the FDA's director of manufacturing and product quality, an action limit is a threshold measurement of contamination "above what would typically be seen in a controlled sterile environment." Yet NECC took no action to investigate or correct this bacterial and mold contamination:

> There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility.

104. Some of the petri dishes used to grow microbes present in environmental samples taken from windowsills, equipment, furniture, floors and other surfaces were "overflowing" with bacteria or fungi in sheets "very visible to the naked eye." Yet NECC did not even bother to investigate what kind of microbes were present.

105. The FDA also reported that samples taken from inside the hoods used for compounding (also inside the ostensibly clean rooms) between January and September 2012 showed at least eight instances of bacterial and/or mold contamination. NECC did not investigate this contamination, did not identify the types of mold or bacteria growing in their ostensibly sterile hoods, nor investigate the impact of this contamination on any of the purportedly sterile products made in the hoods on the days the samples were taken. "[NECC] has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

106. The FDA also observed that a plastic and mattress recycling facility next door produced dust and other airborne contaminants. NECC's HVAC units on the roof were about 100 feet from the recycling facility. Inside NECC, the FDA observed that dark particulate and white, filamentous substances covered the louvers of an HVAC return located behind the autoclave in the clean room.

107. The FDA also observed that the air-conditioning in the clean rooms was turned off overnight. This is not typical for a clean room, as temperatures need to be kept constant to minimize microbial growth.

108. The FDA also observed that a boiler located within 30 feet of the entrance to one of the "Prep Room" was leaking water into puddles. The wet floor around the boiler was soiled with thick white debris and thick black granular material.

109. The mat at the entrance of the Prep Room was brown and soiled. In other words, it was filthy.

110. The FDA also observed cloudy discoloration on the barrier facing the ISO 6 Clean Room and metal surfaces of the pass through in the wall to the ISO 6 Clean Room. The metal ledge within the clean room contained reddish-brown and cloudy substances. And there were "dark, hair like discoloration" along the gasket and crevices located at the bottom edge of the closed pass through installed within the wall of the ISO 6 Clean Room. NECC used ISO 6 Clean Room to formulate and fill sterile preparation, including methylprednisolone.

I. NECC's sterility testing, when done at all, did not comply with USP standards.

111. In May, Analytical Research Laboratories of Oklahoma City tested two five-milliliter vials of steroids produced by New England Compounding Center and found them to be sterile. These vials came from a batch included in one of the three lots implicated by federal and state officials in a multi-state outbreak of meningitis. The report cautioned that it was preliminary and a follow-up would be issued if a problem was detected. According to experts, the sample size was too small to be meaningful and did not comply with the industry standard USP guidelines. Under the USP standard, given the batch size of more than 6,000 vials, the lab should have tested at least 20.

112. For a test to detect contamination with 95% confidence, 18% of the batch would have to be tested.

113. Analytical Research's CEO called for looser testing standards for compounders in a 2007 article in the International Journal of Pharmaceutical Compounding. He claimed that

testing the industry-recommended number of samples could be expensive or impractical for compounders and that 14-day sample quarantine could be an "untenable situation" for a patient waiting for medication.

J. The investigation grows, now covering other drugs and related corporate entities.

1. The DPH shuts down Ameridose and suspends Cadden's pharmacy license.

114. *October 8, 2012* – At the DPH and FDA's insistence, Barry Cadden and Glenn Chin, leaders at NECC, agreed to stop practicing as pharmacists until the investigation is complete.

115. *October 10, 2012* – DPH asked Ameridose and Alaunus Pharmaceuticals to cease all operations, including dispensing, manufacturing, or distributing any products as of 3:00 pm on October 10 through at least October 22. This is later extended through at least November 5, 2012.

116. Also on October 10, 2012, DPH demanded that Barry Cadden immediately resign as manager, director and from any other management position at NECC, Ameridose, and Alaunus.

117. Also on October 10, 2012, the Massachusetts Board of Pharmacy issued an advisory to all pharmacies and pharmacists in Massachusetts emphasizing that all of their actions must be performed in accordance with the USP. The advisory also reiterated that state law requires compounding pharmacies and pharmacists to have a patient-specific prescription from an authorized practitioner when compounding and dispensing medication.

2. The FDA confirms that other NECC products may be contaminated.

118. *October 15, 2012* –The FDA issued an advisory that a patient may have acquired fungal meningitis from a different steroid injection, triamcinolone acetonide. DPH

epidemiologists began outreach to all 192 facilities in Massachusetts who received *any NECC injectable products.*

119. Also on October 15, 2012, the FDA reported a transplant patient with Aspergillus funigatus infection who received NECC cardioplegic solution during surgery. DPH asked Massachusetts providers to contact any patients who received any injectable product, including opthalmis drugs or cardioplegia solutions prepared by NECC after May 21, 2012.

3. The FDA and DPH investigate Ameridose and Alaunus Pharmaceuticals.

120. *October 18, 2012* – The FDA confirmed the presence of fungal contaminates in sealed vials of methylprednisolone acetate in a suspect lot prepared by NECC. The FDA also collects samples from sealed vials of completed product at Ameridose. Results are currently pending with the FDA.

121. *October 19, 2012* – DPH and FDA investigators scrutinized business practices of Alaunus Pharmaceuticals and potential for inappropriate distribution of NECC or Ameridose products. DPH insisted that Ameridose and Alaunus extend their shut down through November 5, 2012.

4. The Board of Pharmacy permanently revokes Cadden and Conigliaro-Cadden's pharmacist licenses.

122. *October 22, 2012* – The Board of Pharmacy and DPH announced that Barry J. Cadden, Glenn A Chin, and Lisa Conigliaro Cadden are prevented from practicing as pharmacists, that it has asked all three to surrender their pharmacist licenses immediately, and that if they do not voluntarily comply their license will be permanently revoked.

5. Ameridose's products are recalled.

123. *October 31, 2012* – Ameridose announced a recall of all of its products. The company sells more than 2,200 drugs in syringes (injectable and oral) and intravenous medicine bags. Federal officials have said Ameridose is part of the investigation because of concerns that it had some of the same business practices as New England Compounding.

124. Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the Food and Drug Administration, said in a telephone interview that the company offered to recall all of its products after federal officials shared the results of their inspection, which found fault with some of its sterility "assurances."

6. The FDA confirms Ameridose's products are contaminated.

125. *November 1, 2012* – the FDA and CDC found bacterial contamination in two other drugs manufactured by NECC, preservative-free betamethasone (a steroid used to help back pain) and cardioplegia solution (used during heart surgery). The FDA found bacteria in three separate batches of betamethasone. Earlier tests had found fungal contamination in the cardioplegia solution. These finding "reinforce the FDA's concern about the lack of sterility in products produced at NECC's compounding facility and serve to underscore that hospitals, clinics, and health care providers should not use any NECC-supplied products." The FDA is still waiting for results of tests for fungal contamination in Ameridose's betamethasone and cardioplegia solution.

126. Also on November 1, 2012, the Massachusetts Board of Registration in Pharmacy passed emergency rules to ensure that compounding pharmacies produce drugs only for patient-specific prescriptions. Compounding pharmacies must submit biannual reports on how many prescriptions they dispensed and where. They must also sign, under the penalty of

perjury, affidavits stating that they are only mixing and dispensing prescriptions for individual patients.

K. Criminal and Congressional Investigations

127. The Department of Justice and the Commonwealth of Massachusetts has announced that they are pursuing criminal investigations of NECC's practices.

128. The U.S. House of Representatives Energy and Commerce Committee is also investigating the outbreak; in particular, the history of investigations and operation at NECC and other companies Cadden was affiliated with that were at any point involved in the production, sale, and/or distribution of drug products. On October 11, 2012, the Committee wrote to Barry Cadden individually to request that NECC preserve all relevant documents and communications and that NECC make arrangements with Committee staff to testify before the Committee before October 18, 2012. Neither Cadden nor anyone else from NECC made themselves available to brief the committee.

129. On October, 22, 2012, the Committee asked Cadden to provide documents from January 1, 2002 through the present , including:

> All documents containing communications referring to relating to any license or inspection of the NECC, Ameridose, and/or Alaunus that [Cadden] sent or received using a personal email account;
>
> All documents containing communications referring or relating to the scope of business conducted by the NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account;
>
> All documents containing communications referring or relating to any safety and/or quality issue related to any product produced, sold, and/or distributed by NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account.

L. Current case counts

130. As of November 2, 2012, the CDC reported 377 cases of fungal meningitis, stroke due to presumed fungal meningitis, or other central nervous system-related infection meeting the outbreak case definition, plus 9 peripheral joint infections (e.g., knee, hip, shoulder, and elbow). The CDC reports cases in Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Tennessee, Texas, and Virginia. Of these 377 reported cases of fungal meningitis, at least 28 people have died (in seven different states).

M. Defendants' assets

131. Both Barry Cadden and Gregory Conigliaro seemed to thrive financially. In 2010, Conigliaro bought a sprawling $3.5 million home in Southborough with six bedrooms, nine bathrooms, and more than 11,000 square feet. He also bought a vacation home in Barnstable in 2008. Meanwhile, the Caddens built a $1.8 million home in Wrentham in 2005.

132. About three years ago, they also purchased and renovated a beach home in North Kingston, R.I., a place with stunning views of Wickford Cove that was featured in Rhode Island Monthly magazine in August.

V. CAUSES OF ACTION

COUNT I – BATTERY

(Against All Defendants)

133. Paragraphs 1 - 132 are incorporated by reference as if set forth fully herein.

134. Defendants NECC, Ameridose, MSM, and their once or current principles and/or employees Gregory Coniglairo, Lisa Coniglairo Cadden, Douglas Conigliaro, Barry Cadden, Carla Conigliaro, and Glenn Chin manufactured and sold poisonous methylprednisone

acetate with the intent that the poisonous product would be injected by physicians into the bodies of customers, including Plaintiff.

135. Defendants NECC, Ameridose, MSM, and their once or current principles and/or employees, Defendants Gregory Coniglairo, Lisa Coniglairo Cadden, Douglas Conigliaro, Barry Cadden, Carla Conigliaro, and Glenn Chin, sold and/or distributed poisonous methylprednisolone acetate that was injected into Plaintiff.

136. Plaintiff was unaware of the substantial health and safety risk inherent in the use of contaminated methylprednisolone acetate manufactured and distributed by the defendants and did not consent to the injection of contaminated methylprednisolone aceate into her body.

137. As a direct and proximate result of Defendants' wrongful acts set forth herein, which caused Plaintiff to be injected with contaminated methylprednisolone acetate, intentionally causing harmful contact with Plaintiff, Plaintiff contracted fungal meningitis and has suffered serious bodily harm, pain and suffering, emotional distress, and has incurred and will continue to incurr financial or economic loss, including but not limited to medical and other expenses. Plaintiff has been damaged in an amount to be determined at trial.

COUNT II – NEGLIGENCE

(Against All Defendants)

138. Paragraphs 1 - 137 are incorporated by reference as if set forth fully herein.

139. As the manufacturer and seller of methylprednisone acetate, Defendants NECC, Ameridose, MSM, and their once or current principles and/or employees, Defendants Gregory Coniglairo, Lisa Coniglairo Cadden, Douglas Conigliaro, Barry Cadden, Carla Conigliaro, and Glenn Chin, owed a duty to Plaintiff to provide methylprednisone acetate which was free of contamination and safe for its intended use.

140. As the principle owner of NECC, and manager of related entities Ameridose and MSM, Gregory Conigliaro Gregory had a substantial role in the manufacture and sale of methylprednisone acetate and knew or should have known of the potential for contamination present in the compounding facility where it was manufactured yet failed to ensure that methylprednisone acetate was compounded in a safe and sterile ennironment, free from contamination and safe for is reasonably intended and foreseeable uses prior to sale. Gregory Conigliaro also had the opportunity and ability to ensure that the product was adequately tested and inspected for contamination prior to sale and failed to do so.

141. As an owner, president and director of pharmacy at NECC and manager of related entitities Ameridose and MSM, and as a practicing licensed pharmacist, Defendant Barry Cadden had a substantial role in the manufacture and sale of methylprednisone acetate and knew or should have known of the potential for contamination present in the compounding facility where it was manufactured, yet failed to ensure that the methylprednisone acetate was compounded in a safe and sterile ennironment, free from contamination and safe for its reasonably intended and foreseeable uses prior to sale. Barry Cadden also had the opportunity and ability to ensure that the product was adequately tested and inspected for contamination prior to sale and failed to do so.

142. As a member of the board of directors of NECC, and as a practicing licensed pharmacist, Defendant Lisa Conigliaro Cadden had a substantial role in the manufacture and sale of methylprednisone acetate and knew or should have known of the potential for contamination present in the compounding facility where it was manufactured, yet failed to ensure that the methylprednisone acetate was compounded in a safe and sterile ennironment, free from contamination and safe for its reasonably intended and foreseeable uses prior to sale.

Lisa Conigliaro Cadden also had the opportunity and ability to ensure that the product was adequately tested and inspected for contamination prior to sale and failed to do so.

143. As someone heavily involved in the day-to-day operations of NECC and as a physician, Douglas Conigliaro had a substantial role in the manufacture and sale of methylprednisone acetate and knew or should have known of the potential for contamination present in the compounding facility where it was manufactured yet failed to ensure that the methylprednisone acetate was compounded in a safe and sterile ennironment, free from contamination and safe for is reasonably intended and foreseeable uses prior to sale. Douglas Coniglairo also had the opportunity and ability to ensure that the product was adequately tested and inspected for contamination prior to sale and failed to do so.

144. As an owner and officer of NECC Carla Conigliaro had substantial responsibility to oversee safe manufacture and sale and knew or should have known of the potential for contamination present in the compounding facility where it was manufactured yet failed to ensure that the methylprednisone acetate was compounded in a safe and sterile ennironment, free from contamination and safe for is reasonably intended and foreseeable uses prior to sale. Carla Conigliaro also had the opportunity and ability to ensure that the productd was adequately tested and inspected for contamination prior to sale and failed to do so.

145. As an empoloyee and leader at NECC, and as a pharmacist, Glenn Chin had a substantial role in the manufacture and sale of methylprednisone acetate and knew or should have known of the potential for contamination present in the compounding facility where it was manufactured yet failed to ensure that the methylprednisone acetate was compounded in a safe and sterile ennironment, free from contamination and safe for is reasonably intended and foreseeable uses prior to sale. Glenn Chin also had the opportunity and ability to ensure that

the product was adequately tested and inspected for contamination prior to sale and failed to do so.

146. Defendants' neglicence caused contamination of the methylprednisone acetate, rendering the product defective, unfit, and/or unreasonably dangerous to end users, including Plaintiff.

147. As a direct and proximate result of Defendants' negligence, lack of care and other wrongful acts set forth herein, which caused Plaintiff to be injected with contaminated methylprednisolone acetate, Plaintiff contracted fungal meningitis and has suffered serious bodily harm, pain and suffering, emotional distress, and has incurred and will continue to incurr financial or economic loss, including but not limited to medical and other expenses. Plaintiff has been damaged in an amount to be determined at trial.

COUNT III – FAILURE TO WARN

(Against All Defendants)

148. Paragraphs 1 - 147 are incorporated by reference as if set forth fully herein.

149. Defendants NECC, Ameridose, MSM, and their once or current principles and/or employees Gregory Coniglairo, Lisa Coniglairo Cadden, Douglas Conigliaro, Barry Cadden, Carla Conigliaro, and Glenn Chin manufactured and sold methylprednisone acetate that was injected into Plaintiff.

150. The methylprednisolone acetate manufactured and sold by Defendants was contaminated and as such posed a substantial health and safety risk to end users, including Plaintiff.

151. As the designer, manufacturer, tester and/or seller of methylprednisolone acetate, Defendants NECC, Ameridose, MSM, and their once or current principles and/or

employees Gregory Coniglairo, Lisa Coniglairo Cadden, Douglas Conigliaro, Barry Cadden, Carla Conigliaro, and Glenn Chin knew or reasonably should have known that its methylprednisolone acetate was contaminated. Defendants knew or reasonably should have known of the substantial health and safety risk its product posed to end users, including Plaintiff.

152. Plaintiff was reasonably unaware of the substantial health and safety risk inherent in the use of contaminated methylprednisolone acetate manufactured and distributed by Defendants.

153. Defendants NECC, Ameridose, MSM, and their once or current principles and/or employees Gregory Coniglairo, Lisa Coniglairo Cadden, Douglas Conigliaro, Barry Cadden, Carla Conigliaro, and Glenn Chin failed to exercise reasonable care to warn consumers, including Plaintiff, of the substantial health and safety risk inherent in the use of its methylprednisolone acetate.

154. As a direct and proximate result of Defendants' failure to warn Plainiff of the health and safetry risk, and other wrongful acts set forth herein, which caused Plaintiff to be injected with contaminated methylprednisolone acetate, Plaintiff contracted fungal meningitis and has suffered serious bodily harm, pain and suffering, emotional distress, and has incurred and will continue to incurr financial or economic loss, including but not limited to medical and other expenses. Plaintiff has been damaged in an amount to be determined at trial.

COUNT IV – LOSS OF CONSORTIUM

(On behalf of Gerrit Erkan Against All Defendants)

155. Paragraphs 1 - 154 are incorporated by reference as if set forth fully herein.

156. Gerrit Erkan, is twelve years of age and lives with his mother. Gerrit Erkan is dependent upon Ms. Erkan for the management of his day-to-day needs as well as for emotional guidance and support. Ms. Erkan was hospitalized as a result of her meningitis putting Gerrit Erkan in fear of losing the companionship of his mother. Upon release from the hospital, Ms. Erkan remained bedridden and unable to fully care for her son's daily physical and emotional needs.

157. As a direct and proximate result of Defendants' negligence, lack of care, failure to warn and other wrongful acts set forth herein, which caused Plaintiff Erkan to be injected with contaminated methylprednisolone acetate, Plaintiff Erkan contracted fungal meningitis. Plaintiff Gerrit Erkan has suffered and will continue to suffer damages, including loss of services, society, companionship, consortium, acts of love and affection, household services, family services of his mother and suffered , and will continute to suffer, mental pain and aguish as a result of his mother's illness.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for relief from the Court against New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, Ameridose LLC, Medical Sales Management, Inc., Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, and Glenn A. Chin as follows:

1. Enter joint and several judgments against the defendants and in favor of Plaintiff;
2. Declare the rights and obligations of the parties as prayed for;
3. Compensate for damages suffered by Plaintiff;
4. Award Plaintiff her costs of suit, including reasonable attorneys' fees as provided by law;
5. Award Plaintiff punitive damages;

6. Award additional damages remedies, and penalties available by law; and

7. Grant such other and further relief the Court deems just and equitable.

VII. JURY DEMAND

158. Pursuant to Fed. Civ. P. 38, Plaintiff, demands a trial by jury on all issues so triable.

Dated: November 2, 2012

Respectfully submitted,

/s/ Thomas M. Sobol
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